



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 168

[EPA-HQ-OPP-2009-0607; FRL-9909-82]

RIN 2070-AJ53

### Labeling of Pesticide Products and Devices for Export

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** EPA is amending the regulations that pertain to labeling of pesticide products and devices intended solely for export. This action will allow placement of the required information on collateral labeling attached to the shipping container of such products rather than on the immediate package of each individual product in such a shipment. This restores provisions that previously allowed exporters to use labeling attached to, or accompanying, the product shipping container of the export pesticide at all times when shipped or held for shipment in the United States.

**DATES:** This direct final rule is effective [*insert date 90 days after date of publication in the Federal Register*].

Written adverse comments must be received on or before [*insert date 30 days after date of publication in the Federal Register*]. If EPA receives adverse comment, EPA will withdraw this direct final rule before its effective date.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2009-0607, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you

consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Kathryn Boyle, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6304; email address: [boyle.kathryn@epa.gov](mailto:boyle.kathryn@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### *A. Does this Action Affect me?*

You may be potentially affected by this action if you export a pesticide product, a pesticide device, or an active ingredient used in producing a pesticide. The following North American Industrial Classification System (NAICS) code category is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include, but are not limited

to: Pesticide and other agricultural chemical manufacturing (NAICS code 325320), e.g., pesticide manufacturing, insecticide manufacturing, herbicide manufacturing, and fungicide manufacturing.

*B. What is the Agency's Authority for Taking this Action?*

This action is issued under the authority of section 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136w(a), to carry out the provisions of FIFRA section 17(a), 7 U.S.C. 136o(a).

*C. What Action is the Agency Taking?*

EPA is revising the regulations that pertain to labeling of pesticide products and devices intended solely for export. This action will allow placement of the required information on collateral labeling attached to a shipping container of such products rather than on the label of each individual product in such a shipment.

*D. What are the Impacts of this Action?*

There are no costs associated with this action, and the benefits provided are related to avoiding potential costs. Without these labeling provisions, registrants would be required to place export-related labeling on the immediate package of each individual pesticide product in a shipping container that is intended solely for export. According to stakeholders, the inability to use the labeling method allowed under the previous regulations could significantly increase their costs and create trade barriers.

## **II. What are the Direct Final Rule Procedures?**

EPA is issuing a direct final rule, which means that the effective date of this direct final rule is [*insert date 90 days after date of publication in the **Federal Register***].

If EPA receives written adverse comments on or before [*insert date 30 days after*

*date of publication in the Federal Register*], EPA will withdraw the direct final rule before its effective date; issue a proposed rule to seek public comment on the issue(s) raised by the adverse comments received, provide a 30-day period for public comment on that issue; and then issue a new final rule.

### **III. Background**

#### *A. Summary of the 2011 Proposed Rule*

On April 6, 2011 (76 FR 18995) (FRL-8862-2), EPA issued a notice of proposed rulemaking (NPRM) titled, “Regulation to Clarify Labeling of Pesticides for Export.” EPA proposed to clarify, restructure, and add specificity to labeling regulations for the export of unregistered pesticide products and devices. In that NPRM, EPA proposed to explicitly require labeling to accompany the unregistered export pesticide product or device at all times, even when such products are being shipped between registered establishments operated by the same producer.

#### *B. Public Comments on the NPRM*

The public comment period for the April 6, 2011, NPRM closed on June 6, 2011, and six sets of comments were submitted. Two of the commenters pointed out several inconsistencies in the use of the terms “label,” “labeling,” and “supplemental labeling” in the proposal. One of those commenters also urged “that all labeling requirements should be in compliance with existing regulations under 40 CFR 156.” The comments are available in the docket under docket ID number EPA-HQ-OPP-2009-0607.

EPA analyzed the comments and prepared a response to comments document, which is available in the docket under document number EPA-HQ-OPP-2009-0607-0016. As part of analyzing the comment on inconsistencies in the use of the terms “label,” “labeling,” and “supplemental labeling,” EPA referred to the FIFRA definitions of “label” and “labeling.”

FIFRA section 2(p)(1) defines label as “the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.” Under FIFRA section 2(p)(2), labeling is a more inclusive term which includes labels as well as “all other written, printed, or graphic matter” that accompanies the product at any time, or to which reference is made on a label or in literature accompanying the pesticide or device. Because the two terms are not interchangeable, EPA agreed that inconsistent use could create confusion. Thus, as EPA began to write the regulatory text for the final rule, the Agency carefully evaluated the regulatory text for possibly confusing uses of the terms “label” and “labeling.”

During that evaluation, and bearing in mind the comment that “all labeling requirements should be in compliance with existing regulations under 40 CFR 156,” EPA analyzed proposed § 168.66(b). This section specified that “the required label information may be fully met by” and then provided several examples of ways to provide the required label information. One of the examples referred to “supplemental labeling.” At that time, EPA determined to provide a reference to the existing label regulations in 40 CFR part 156, instead of providing examples of ways to meet the required label information. Specifically, EPA referred to 40 CFR 156.10(a)(4), which is titled “Placement of Label,” believing that provision would provide appropriate and accurate information.

### *C. The 2013 Final Rule*

The final rule titled “Labeling of Pesticide Products and Devices for Export; Clarification of Requirements” published on January 18, 2013 (78 FR 4073) (FRL-9360-8). The rule was effective on March 19, 2013, with a compliance date of January 21, 2014.

#### **IV. This Direct Final Rule**

Industry stakeholders subsequently brought to the Agency's attention their concern that removing the term "supplemental labeling" resulted in the removal of a provision stating that such supplemental labeling can be attached to a shipping container holding export pesticides or devices rather than to each individual product container in a shipment. They stated that the inability of registrants to use "supplemental labeling" in that manner could create trade barriers and increase costs. The purpose of this direct final rule is to address those concerns.

EPA now believes that the term "supplemental labeling" is not the appropriate term to describe the material or documentation used to meet the requirements of the export labeling rules. To more accurately describe the materials other than "labels" that are acceptable for meeting these requirements, EPA believes that a better term is "collateral labeling." EPA has already described collateral labeling in the Label Review Manual (LRM), page 3-2 (see <http://www.epa.gov/oppfead1/labeling/lrm/chap-03.pdf>) as follows:

Bulletins, leaflets, circulars, brochures, data sheets, flyers or other written, printed or graphic matter which are referred to on the label or which are to accompany the product are known in Agency practice as "collateral labeling." Such labeling is subject to applicable requirements of FIFRA and the Agency's regulations.

Accordingly, in this direct final rule EPA is using the term "collateral labeling" in restoring the ability of exporters to comply with export labeling requirements through materials that are not attached to each individual export product's immediate container. EPA is revising existing 40 CFR 168.66 to remove the reference to 40 CFR 156.10(a)(4), and to restore the inadvertently eliminated provisions that allowed exporters to use such collateral labeling attached to, or accompanying, the product shipping container of

the export pesticide at all times when shipped or held for shipment in the United States. EPA will also restructure 40 CFR part 168, subpart D, by moving the text in §168.68 and some of the text in §168.66 to new §168.65.

## **V. FIFRA Review Requirements**

In accordance with FIFRA section 25(a), EPA submitted the draft direct final rule to the Secretary of Agriculture (USDA), the FIFRA Scientific Advisory Panel (SAP), and appropriate Congressional Committees. On February 10, 2014, the FIFRA SAP waived its review of this direct final rule because the changes “are administrative in nature and do not contain scientific issues that require the SAP's consideration.” On March 12, 2014, USDA waived review of this direct final rule, because this action merely “corrects the regulatory text.”

## **VI. Statutory and Executive Order Reviews**

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This direct final rule is not a "significant regulatory action" under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and was not, therefore, submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

### *B. Paperwork Reduction Act (PRA)*

According to the PRA, 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA regulations in

title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, as applicable.

The information collection requirements associated with reporting under 40 CFR part 168 have already been approved by OMB pursuant to PRA under OMB control number 2070-0027 (EPA ICR No. 0161). This direct final rule is not expected to involve an increase in information collection activities and there are no additional burdens imposed by this direct final rule that requires additional review or approval by OMB.

*C. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* In making this determination, the impact of concern is any significant adverse economic impact on small entities, because the primary purpose of a final regulatory flexibility analysis is to identify and address regulatory alternatives that “minimize the significant economic impact on small entities” 5 U.S.C. 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule has no net burden effect on the small entities subject to the rule. As indicated previously, EPA is restoring a provision that was inadvertently removed from the regulation. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

*D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any State, local or tribal governments, because no State, local, or tribal government is known to produce, transport, formulate, package, or



export unregistered pesticide products or devices. As indicated previously, EPA is restoring a provision that was inadvertently removed from the regulation. As such, the action will have a net affect on producers, transporters, formulators, packagers, and exporters of unregistered pesticide products and devices intended solely for export.

*E. Executive Order 13132: Federalism*

This action will not have substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

*F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications because it is expected to only affect producers, transporters, formulators, packagers, and exporters of unregistered pesticide products and devices. Since no Indian tribal government is known to produce, transport, formulate, package, or export unregistered pesticide products or devices, this action has no tribal implications. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000) do not apply to this action.

*G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this action does not address environmental health or safety risks disproportionately affecting children.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

*I. National Technology Transfer and Advancement Act (NTTAA)*

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. As such, this action does not entail special considerations of environmental justice-related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

**VII. Congressional Review Act (CRA)**

Pursuant to the CRA, 5 U.S.C. 801 *et seq.*, EPA will submit a report containing this direct final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the direct final rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 168**

Environmental protection, Administrative practice and procedure, Advertising, Exports, Labeling, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 24, 2014.

James Jones,

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 168--[AMENDED]**

1. The authority citation for part 168 continues to read as follows:

**Authority:** 7 U.S.C. 136-136y.

2. Revise the heading for subpart D to part 168 to read as follows:

**Subpart D--Procedures for Exporting Pesticides**

3. Add § 168.65 to subpart D to read as follows:

**§ 168.65 Applicability.**

(a) This subpart describes the labeling requirements applicable to pesticide products and devices that are intended solely for export from the United States under the provisions of FIFRA section 17(a).

(b) This subpart applies to all export pesticide products and export pesticide devices that are exported for any purpose, including research.

(c) Export pesticide products and export pesticide devices are also subject to requirements for pesticide production reporting, recordkeeping and inspection and purchaser acknowledgement provisions that can be found in the following parts:

(1) Pesticide production reporting requirements under FIFRA section 7 are located in part 167 of this chapter (as referenced in § 168.85(b)).

(2) Recordkeeping and inspection requirements under FIFRA section 8 are located in part 169 of this chapter (as referenced in § 168.85(a)).

(3) Purchaser acknowledgement statement provisions under FIFRA section 17(a) are located in § 168.75.

4. Revise § 168.66 to read as follows:

**§ 168.66 Labeling of pesticide products and devices for export.**

Any label and labeling information requirements in §§ 168.69, 168.70, and 168.71 that are not met fully on the product label attached to the immediate product container may be met by collateral labeling that is either:

- (a) Attached to the immediate product (container label); or
- (b) Attached to or accompanies the shipping container of the export pesticide or export device at all times when it is shipped or held for shipment in the United States.

**§ 168.68 [Removed and Reserved]**

5. Remove and reserve § 168.68.
6. Revise § 168.69(a) to read as follows:

**§ 168.69 Registered export pesticide products.**

(a) Each export pesticide product that is registered under FIFRA section 3 or FIFRA section 24(c) must bear labeling approved by EPA for its registration or collateral labeling in compliance with § 168.66.

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7. Revise § 168.70(b) to read as follows:

**§ 168.70 Unregistered export pesticide products.**

\* \* \* \* \*

(b) Each unregistered export pesticide product must bear labeling that complies with all requirements of this section or collateral labeling in compliance with § 168.66.

\* \* \* \* \*

8. Revise § 168.71(a) to read as follows:

**§ 168.71 Export pesticide devices.**

(a) Each export pesticide device sold or distributed anywhere in the United States must bear labeling that complies with all requirements of this section or collateral labeling in compliance with § 168.66.

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[FR Doc. 2014-09843 Filed 04/25/2014 at 4:15 pm; Publication Date: 04/30/2014]